

1. (cancelled).

2. (previously amended): A method according to claim 28, wherein step (α) is carried out in an anhydrous medium.

3-5. (cancelled).

6. (previously amended): A method according to claim 28, wherein the nanodispersion comprises as component

(a) a phospholipid, a hydrated or partially hydrated phospholipid, a lysophospholipid, or mixtures thereof.

7-14. (cancelled).

15 (previously amended): A Method according to claim 28, which is characterised in that the pharmaceutical formulation is a liquid, semisolid or solid preparation.

16. (previously amended): A pharmaceutical liquid formulation in the form of an injectable solution, infusion solution, drops, spray, aerosol, emulsion, lotion, suspension, drinking solution, gargle or inhalant, which comprises a nanodispersion as defined in claim 29.

17. (previously amended): A pharmaceutical semisolid formulation in the form of an ointment, oil-in-water emulsion, water-in-oil emulsion, gel, lotion, foam, paste, suspension, ovula or plaster, which comprises a nanodispersion as defined in claim 29.

18. (currently amended): A pharmaceutical solid formulation in the form of a tablet, coated tablet, capsule, granules granule, effervescent granules, effervescent tablet, lozenge, sucking and chewing tablet, suppositories suppository, implant, lyophilisate, adsorbate or powder, which comprises a nanodispersion as defined in claim 29.

19. (previously amended): A matrix- or membrane-controlled pharmaceutical application system in the form of an oros capsule, transdermal system or injectable microcapsule, which comprises a nanodispersion as defined in claim 29.

20. (previously amended): A pharmaceutical formulation according to claim 16, wherein the nanodispersion is present in the aqueous phase.

21. (previously amended): A pharmaceutical formulation according to claim 16, wherein the nanodispersion is present in the aqueous phase in a concentration of 0.01 to 100 % by weight.

*C 1
C 2
C 3*
22-27. (cancelled).

28. (currently amended): A method of preparing a pharmaceutical formulation of a lipophilic pharmaceutical active agent in the form of an aqueous highly homogeneous nanodispersion having a Gaussian distribution, which steps consist essentially of

(α) mixing the components

- (a) 0.1 to 30 % by weight of a phospholipid,
- (b) 1 to 50 % by weight of a polyoxyethylene coemulsifier selected from the group consisting of polyethoxylated fatty alcohols, polyethoxylated fatty acids, polyethoxylated vitamin E derivatives, polyethoxylated lanolin and derivatives thereof, polyethoxylated fatty acid partial glycerides, polyethoxylated alkylphenols, polyethoxylated fatty alcohols and salts thereof, polyethoxylated fatty amines and fatty acid amides and polyethoxylated carbohydrates,
- (c) 0.1 to 80 % by weight of a lipophilic component which comprises a natural or synthetic or a partially synthetic C₄-C₁₈triglyceride, and a lipophilic pharmaceutical active agent, in which aqueous nanodispersion any pharmaceutically active agent is lipophilic and is always present in component (c), and
- (d) 0.63 to 14.2 % by weight of ethanol, with the proviso that the sum of (a), (b), (c) and (d) is 100 % by weight,

in conventional stirring apparatus until a homogeneous clear liquid is obtained and

(β) adding the liquid obtained in step (α) to a water phase, wherein (β) is carried out in the absence of high shear or cavitation forces, and wherein the particles in the nanodispersion have an average diameter <50 nm.

29. (currently amended): An aqueous highly homogeneous nanodispersion of a lipophilic pharmaceutical active agent having a Gaussian distribution, which consists essentially of

- (a) 0.1 to 30 % by weight of a phospholipid,
- (b) 1 to 50 % by weight of a polyoxyethylene coemulsifier selected from the group consisting of polyethoxylated fatty alcohols, polyethoxylated fatty acids, polyethoxylated vitamin E derivatives,

polyethoxylated lanolin and derivatives thereof, polyethoxylated fatty acid partial glycerides,
polyethoxylated alkylphenols, polyethoxylated fatty alcohols and salts thereof, polyethoxylated fatty
amines and fatty acid amides and polyethoxylated carbohydrates,

(c) 0.1 to 80 % by weight of a lipophilic component which comprises a natural or synthetic or a partially synthetic C₄-C₁₈triglyceride, and a lipophilic pharmaceutical active agent, in which aqueous nanodispersion any pharmaceutically active agent is lipophilic and is always present in component (c), and

(d) 0.63 to 14.2 % by weight of ethanol, with the proviso that the sum of (a), (b), (c) and (d) is 100 % by weight, plus

(e) a water phase.

which formulation is obtainable by

(c) mixing the components (a), (b), (c), and (d) until a homogeneous clear liquid is obtained, and

(B) adding the liquid obtained in step (a) to the water phase, wherein step (B) is carried out in the

absence of high shear or cavitation forces, and whereby the particles in the nanodispersion have an average diameter <50 nm.